

AUBREY INC.

AWBAT Plus Wound Dressing
Traditional 510(k)

SECTION 5: 510(k) Summary

JAN 21 2010

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

5.1 Name, Address, Phone and Fax Number of the Applicant

Aubrey Inc.

5930 Sea Lion Place, Suite 100

Carlsbad, CA 92010

Phone: (760) 602-8303

Fax: (760) 602-8304

5.2 Contact Person

Aubrey Woodroof, PhD, MBA

Chairman and CEO

Aubrey Inc.

5930 Sea Lion Place, Suite 100

Carlsbad, CA 92010

Phone: (760) 602-8303

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5.3 Date Prepared

22 June 2009

5.4 Device

Name: AWBAT Plus

Trade Names: AWBAT-S Plus, AWBAT-D Plus, AWBAT-M Plus

Common Name: Wound Dressing, Collagen

Classification Name: Unclassified Dressing

Product Code: FRO

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Name: AWBAT

Trade Names: AWBAT-S, AWBAT-D, AWBAT-M

Common Name: Wound Dressing, Collagen

Classification Name: Unclassified

Product Code: KGN

5.6 Device Description

A Temporary Wound Dressing for coverage of Superficial burns, Donor sites and Meshed autografts until healing occurs. AWBAT Plus is composed of a single or multiple filament knitted nylon fabric, bonded to a thin porous silicone membrane (approximately 0.001 inch). The nylon side of these components is coated with a non-toxic mixture of porcine collagen peptides, chondroitin-4-sulfate, chondroitin-6-sulfate, Immuno-10 (Aloe polysaccharides), vitamin C, vitamin E, and polysorbate 20.

AWBAT Plus is manufactured in 12"x12" sheets that are cut to sizes of 6"x6", 6"x12" and 12"x12" and ink stamped AWBAT-S Plus, AWBAT-D Plus, AWBAT-M Plus accordingly.

AWBAT-S Plus has pores in the silicone membrane at 1/4" centers and the approximate area of an AWBAT-S Plus pore is 0.0036 square inch each.

AWBAT-D Plus has pores in the silicone membrane at 1/4" centers and the approximate area of an AWBAT-D Plus pore is 0.0073 square inch each.

AWBAT-M Plus has pores in the silicone membrane at 1/4" centers and the approximate area of an AWBAT-M Plus pore is 0.0070 square inch each.

The following table addresses the Design and Use of the Device:

Table 1: Design and Use of the Device

Question	Yes	No
Is the intended device for prescription use?	Yes*	
Is the intended device for over-the-counter use?		No
Does the device contain components derived from a tissue or other biological source?	Yes**	
Is the device provided sterile?	Yes	
Is the device intended for single use?	Yes	
Is the device a reprocessed single use device?		No
If yes, does this device type require reprocessed validation data?		N/A
Does the device contain a drug?		No
Does the device contain a biologic?	Yes**	
Does the device use software?		No

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Question	Yes	No
Does the submission include clinical information?		No
Is the device implanted?		No

*AWBAT is intended for application by a physician.

**AWBAT contains biological components: porcine type 1 collagen (gelatin), chondroitin sulfate, Immuno-10 (Aloe polysaccharides), vitamin C and vitamin E.

AWBAT-S Plus is composed of a 15/2 denier multiple filament nylon knitted fabric, bonded to a thin porous silicone membrane. The nylon side of these components is coated with a non-toxic mixture of porcine collagen peptides, chondroitin-4-sulfate, chondroitin-6-sulfate, Immuno-10 (Aloe polysaccharides), vitamin C, vitamin E, and polysorbate 20.

AWBAT-D Plus has the same composition as AWBAT-S Plus, except it is more porous to enable the clinician to evacuate a clot through the membrane into an outer sterile wrap.

AWBAT-M Plus has the same composition as AWBAT-D Plus, except the 12/1 denier nylon fabric is monofilament (thinner & less adherent).

AWBAT Plus, like AWBAT, can be manufactured in flat sheets or shaped into gloves, socks or masks.

5.7 Device Intended Use

Temporary wound dressing for coverage of Superficial burns, Donor sites and Meshed autografts.

AWBAT-S Plus: is intended for clean Superficial burn wounds.

AWBAT-D Plus: is intended for Donor sites after hemostasis has been established.

AWBAT-M Plus: is intended to be used as a protective covering for Meshed autografts.

5.8 Technological Characteristics of Device Compared to Predicate Device

The following Table describes the comparative characteristics of AWBAT Plus and AWBAT.

Table 2: Comparative Characteristics

Characteristic	AWBAT Plus	Predicate(s)
Intended Use/Indications for Use	<p>AWBAT-S Plus is intended for clean, Superficial burn wounds.</p> <p>AWBAT-D Plus is intended for Donor sites after hemostasis has been established.</p>	<p>Same intended use as AWBAT-S standard (K082869).</p> <p>Same intended use as AWBAT-D standard (K082869).</p>

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Characteristic	AWBAT Plus	Predicate(s)
	AWBAT-M Plus is intended for use as a protective covering for Meshed autografts.	Same intended use as AWBAT-M standard (K082869).
Target Population	Burn Victims (AWBAT-S Plus). Patients who have had skin removed (donor site) to apply to another body site (AWBAT-D Plus). Patients who have had skin grafts (AWBAT-M Plus)	Same as AWBAT-S standard (K082869). Same as AWBAT-D standard (K082869). Same as AWBAT-M standard (K082869).
Where Used	Hospital	Same as AWBAT standard (K082869).
Design	Thin porous silicone membrane, mechanically bonded to a knitted bifilament nylon fabric, coated with a non-toxic mixture of porcine collagen peptide, and hydrophilic components (see materials, below) (AWBAT-S Plus and AWBAT-D Plus) Thin porous silicone membrane, mechanically bonded to a knitted monofilament nylon fabric, coated with a non-toxic mixture of porcine collagen peptide, and hydrophilic components (see materials, below) (AWBAT-M Plus)	Similar to AWBAT-S and AWBAT-D standard (K082869): Thin porous silicone membrane, mechanically bonded to a knitted bifilament nylon fabric, coated with a non-toxic mixture of porcine collagen peptide. Similar to AWBAT-M standard (K082869): Thin porous silicone membrane, mechanically bonded to a knitted monofilament nylon fabric, coated with a non-toxic mixture of porcine collagen peptide.
Materials: Nylon	Nylon fabric made from 15/2 denier yarn (AWBAT-S Plus and AWBAT-D Plus) Nylon fabric made from 12/1 denier yarn (AWBAT-M Plus)	Same as AWBAT-S and AWBAT-D standard (K082869) Same as AWBAT-M standard (K082869)
Silicone	Silicone (approx 0.001 inch)	Same as AWBAT standard (K082869)
Collagen	Porcine gelatin	Same as AWBAT standard (K082869)
Chondroitin sulfate	Chondroitin-4-sulfate and chondroitin-6-sulfate	Chondroitin-6-sulfate same as Integra (P900033)
Immuno-10, Vitamin C, vitamin E and Polysorbate 20	Immuno-10, Vitamin C, vitamin E and Polysorbate 20	None
Porosity	6.0% (AWBAT-S Plus) 12.0% (AWBAT-D Plus) 11.0% (AWBAT-M Plus)	Same as AWBAT-S standard (K082869) Same as AWBAT-D standard (K082869) Same as AWBAT-M standard (K082869)
Occlusiveness	94.0% (AWBAT-S Plus)	Same as AWBAT-S standard (K082869)

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Characteristic	AWBAT Plus	Predicate(s)
	88.0% (AWBAT-D Plus)	Same as AUBAT-S standard (K082869)
	89.0% (AWBAT-M Plus)	Same as AUBAT-S standard (K082869)
Sterilization Method	Electron Beam Radiation	Same as AUBAT standard (K082869).
Shelf Life	3 years	Same as AUBAT standard (K082869).
Sizes	6"x6", 6"x12", 12"x12"	Same as AUBAT standard (K082869).

5.9 Device Testing

Biocompatibility testing is being conducted per FDA recognized consensus standard ISO 10993-1:2003 for the materials used to manufacture the AUBAT product family to assure they are safe for its intended use. Aubrey Inc. certifies that it will not distribute AUBAT Plus until this testing is completed and demonstrates compliance with the requirements of FDA recognized consensus standard ISO 10993-1:2003.

Per ISO 10993-1:2003, AUBAT Plus is categorized as follows (from Table 1 of the standard):

- Contact Duration: (B), Prolonged
- Body Contact Category: Surface Device
- Body Contact Type: Breached or compromised surface

Per Table 1 of ISO 10993-1:2003, the following testing is indicated:

- Cytotoxicity
- Sensitization
- Irritation or intracutaneous reactivity.

The manufacturing process of the AUBAT product family complies with the United States Food and Drug Administration and European Standards for the manufacturing of medical devices.

5.10 Substantial Equivalence Summary

The submitted material in this Premarket Notification demonstrates that AUBAT Plus wound dressing (AWBAT-S Plus, AUBAT-D Plus and AUBAT-M Plus) is substantially equivalent to the AUBAT wound dressing (K082869) in terms of intended use, materials, design, function

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and operating characteristics. Both AWBAT and AWBAT Plus are Temporary Wound Dressings for coverage of Superficial burns, Donor sites and Meshed autografts until healing occurs. Both AWBAT and AWBAT Plus are composed of the same three base components in the same configurations: nylon, silicone, and collagen peptides. Additionally, AWBAT Plus contains hydrophilic components Immuno-10 (Aloe polysaccharides) and chondroitin-4-sulfate/chondroitin-6-sulfate ~~for enhancing the creation of a~~ moist wound healing environment. In conjunction, small amounts of anti-oxidant components, vitamin E oil and vitamin C crystals, are added to protect the hydrophilic components during the manufacturing process, with a small amount polysorbate 20 included to emulsify the vitamin E oil.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

JAN 21 2010

Aubrey, Inc.
% Shepard G. Bentley
5930 Sea Lion Place, Suite 100
Carlsbad, California 92010

Re: K091863

Trade/Device Name: AWBAT Plus (AWBAT-S Plus, AWBAT-D Plus, AWBAT-M Plus)

Regulation Number: Unclassified

Product Code: FRO

Dated: December 17, 2009

Received: December 28, 2009

Dear Shepard G. Bentley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

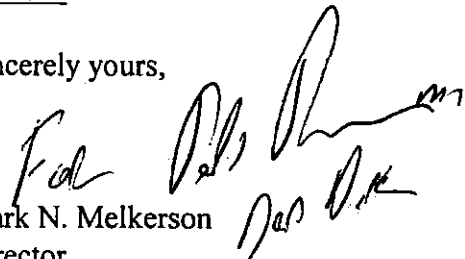
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR-regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091863

Device Name: AWBAT Plus (AWBAT-S Plus, AWBAT-D Plus, AWBAT-M Plus)

Indications for Use:

AWBAT-S Plus: is intended for clean Superficial burn wounds.

AWBAT-D Plus: are intended for Donor sites after hemostasis has been established.

AWBAT-M Plus: are intended to be used as a protective covering for Meshed autografts.

Prescription Use X

(Part 21 CFR 801 Subpart D)

Over-The-Counter Use

AND/OR (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Daniel Krause for M. Kim
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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